



Convergence of Communications and Medical Devices

Current State and Lessons Learned

Jorge Valdes

Chief Technical Officer, DexCom, Inc.

July 26, 2010

seven⁺PLUS
continuous glucose monitoring system

Convenience + Performance + Simplicity



Everyday in the US...

- ❖ 1 in 3 children born will develop diabetes
- ❖ 4,100 people will be diagnosed
- ❖ 55 people with diabetes will go blind
- ❖ 230 amputations will be performed
- ❖ 120 will enter treatment for kidney failure

1 in 10 health care dollars is spent treating diabetes

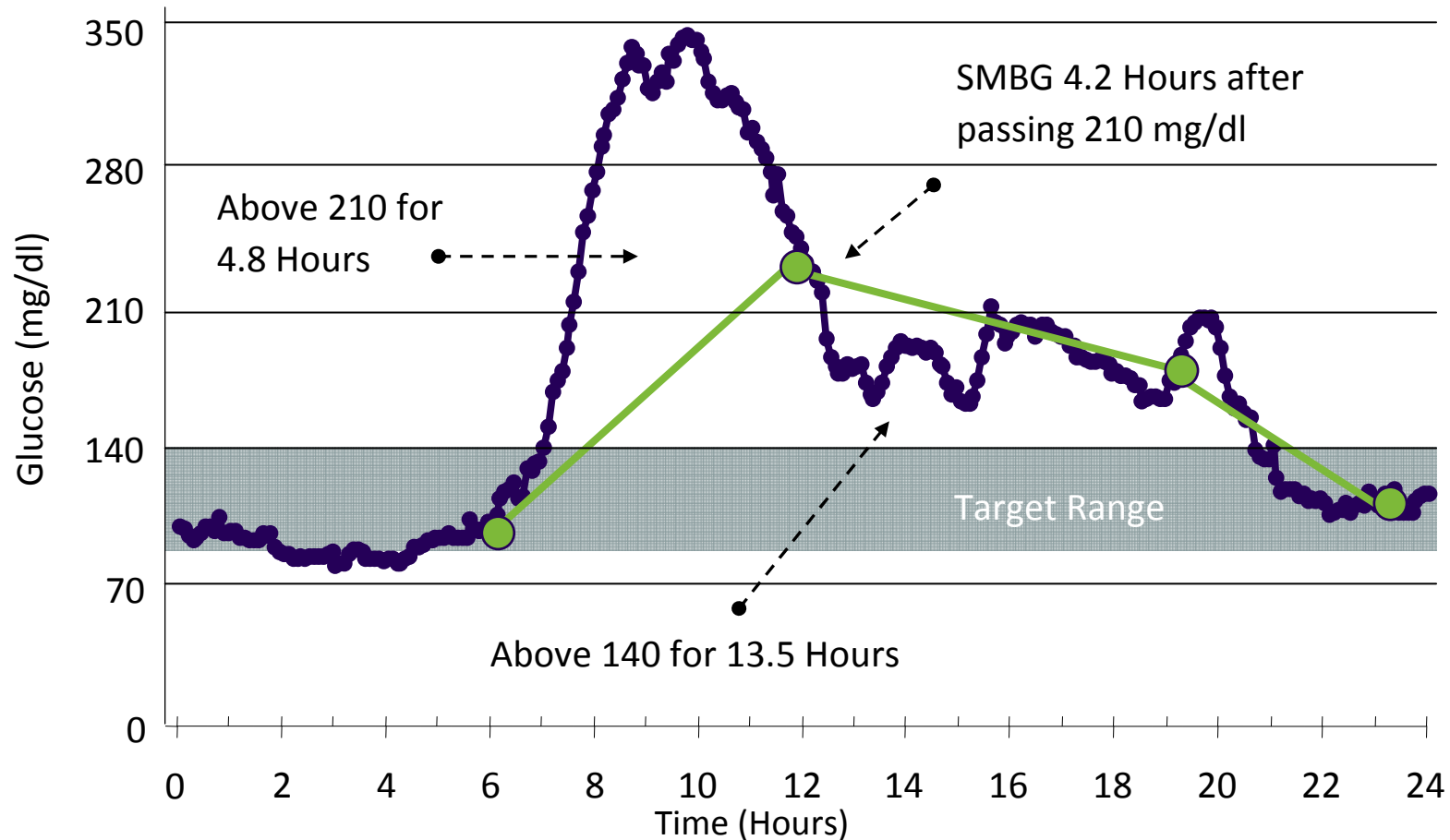
Kleinfeld N.R. NYT, "Diabetes and Its Awful Toll Quietly Emerge as a Crisis" 1/9/2006



severin+PLUS
continuous glucose monitoring system

 **dexcom**
THE GLUCOSE SENSOR COMPANY

Why Continuous Glucose Monitoring?



Target Range



severin+PLUS
continuous glucose monitoring system

dexcom
THE GLUCOSE SENSOR COMPANY

Current State: The DexCom System



The Sensor

- ▶ Small & Comfortable
- ▶ Water Resistant
- ▶ The Only 7 day Sensor



The Transmitter

- ▶ Wireless
- ▶ Unique Micro-technology



The Receiver

- ▶ Portable & Lightweight
- ▶ Trending Screens
- ▶ High & Low Glucose Alerts



sever+PLUS
continuous glucose monitoring system

Current State: DexCom and Wireless Communications

- First Generation Wireless Technology (2006)
 - Uni-directional 402MHz (MICS Band) communication
 - FCC Waiver for 402MHz accelerates product introduction
- FDA approves 3-day product (2006)
- FDA approves the first 7-day CGM product (2007)
- FCC modification of rules provides DexCom critical time to transition from MICS band (expires 2013)
- Through intelligent regulation we have improved patient's lives
 - The regulatory flexibility shown by both the FCC and FDA has allowed people with diabetes faster access to devices that help them better manage their disease



severin+PLUS
continuous glucose monitoring system

 **dexcom**
THE GLUCOSE SENSOR COMPANY

Wireless Technology and Diabetes

- All three FDA approved CGM products use wireless technology to communicate between the body-worn glucose sensor and the primary display device
- Several BG meters use wireless technology to connect to PCs
- Some BG meters use cellular technology to upload data to physicians
- Several insulin pumps use hand-held wireless controllers
- Multiple next generation devices are pursuing integration with Smart Phones



severin+PLUS
continuous glucose monitoring system

 **dexcom**
THE GLUCOSE SENSOR COMPANY

Wireless Technology and Diabetes Lessons Learned

- Regulatory flexibility, hard to envision every possible use case
- Patients are consumers and have same expectations for hand-held devices
- Body-worn sensors must be very small and not interfere with everyday life
- Wireless technology plays a critical role in providing medical applications with greater flexibility, comfort, and ease of use



severin+PLUS
continuous glucose monitoring system

 **dexcom**
THE GLUCOSE SENSOR COMPANY

What DexCom Suggests

- DexCom is grateful to the FCC and FDA for holding this forum and recognizing the need for regulatory certainty by medical device and communications equipment manufacturers
 - FCC and FDA should continue to provide regulatory flexibility in order to allow the convergence of communications and medical devices
 - Each agency should regulate within their own area of expertise
 - The medical community should leverage the technology already defined, implemented, and tested through the different standards of the data & telecommunication industry in order to ensure reliability and security for medical applications



severin+PLUS
continuous glucose monitoring system

 **dexcom**
THE GLUCOSE SENSOR COMPANY

What Does the Future Hold?

- Wireless communication opens up a world of opportunities for medical devices, allowing for improved and more cost effective patient care and greater patient safety.
 - Peace of mind for parents via text messaging of diabetic children's blood glucose level
 - Security at night via text messaging of unacknowledged low alerts to family or medical provider
 - Reduced treatment and travel costs through remote monitoring of patient glucose levels



severin+PLUS
continuous glucose monitoring system

 **dexcom**
THE GLUCOSE SENSOR COMPANY